



NTP
National Toxicology Program

CERHR Chemical Nomination and Selection Process

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Outline of Talk

- CERHR Activities and Products
- Status of Reports
- Selection Criteria and Process
- Bisphenol A Nomination and Selection
- Lead Nomination Currently Under Consideration
- Question for the NTP Board of Scientific Counselors



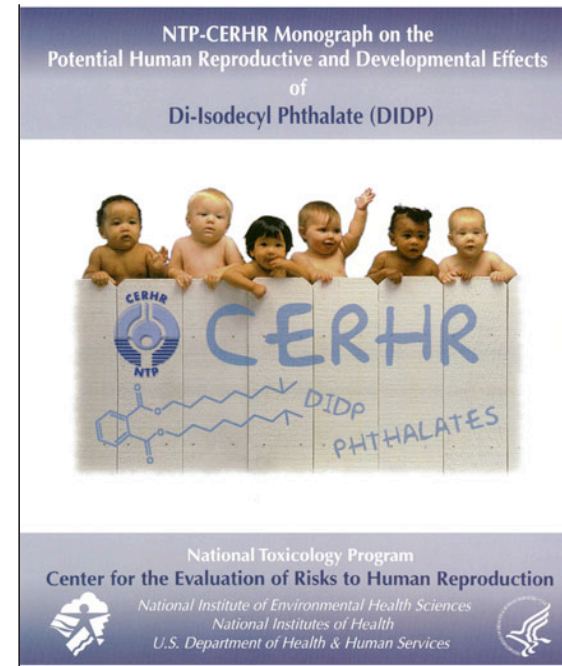
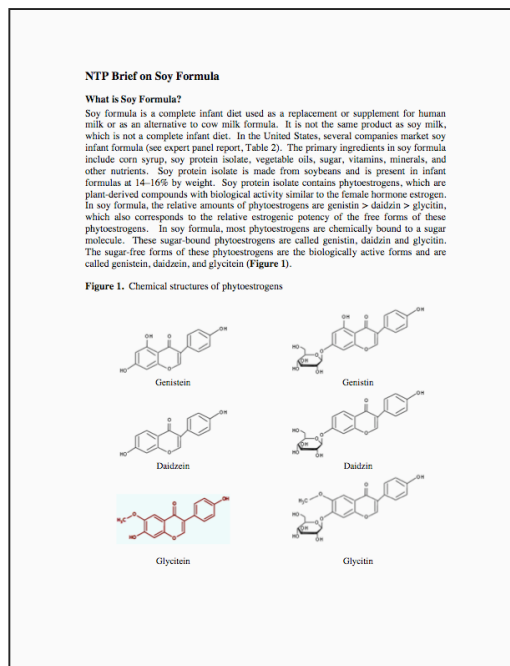
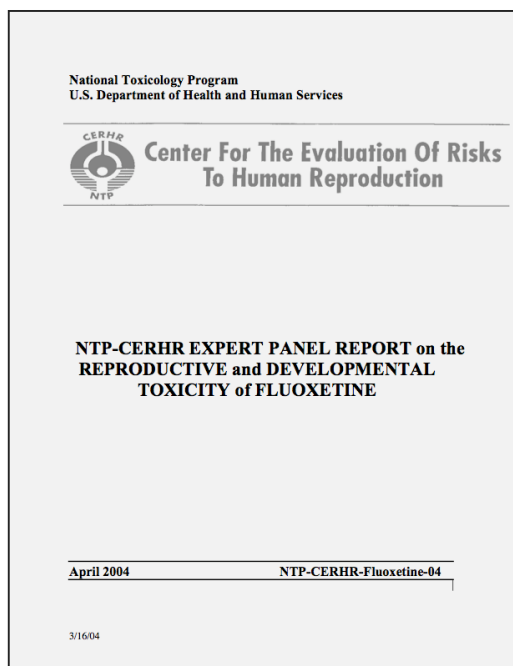
Main Activities of CERHR

- Convene expert panels to evaluate selected chemicals for effects on human reproduction and development
- Maintain a website for information and communication
- Respond to individual inquiries on reproductive health issues



Main Products of CERHR

- CERHR Expert Panel Reports
- NTP Briefs
- NTP-CERHR Monographs





NTP-CERHR Reports

- 16 NTP-CERHR Monographs released since the series started in 2003
 - DEHP Monograph will be released soon
- NTP Briefs on Soy Formula and Genistein
 - Available for public comment through December 8
 - Undergoing external peer review
- Draft Expert Panel Report on Hydroxyurea available for public comment through December 15
- Draft Expert Panel Report on Bisphenol A will be released for public comment on December 15



Nomination and Selection Process

- Chemicals nominated via NTP or CERHR websites
- CERHR Core Committee reviews preliminary dossiers at quarterly meetings
- CERHR prepares full dossiers on chemicals of interest
- Core Committee reviews full dossiers and recommends/selects chemicals for expert panel evaluation
- Recommended chemicals sent to NTP Associate Director for review and approval
- CERHR announces approved/selected chemicals in the Federal Register and invites public comments



Chemical Selection Factors

- Potential for human exposures
- Extent of data from reproductive and developmental toxicity studies
- Production volume
- Public concern



Bisphenol A Nomination

- Nominated for evaluation in 2001
- Deferred because of NTP/NIEHS/EPA workshop: “Endocrine Disruptors Low-Dose Peer Review - October 2000”
- Reconsidered by the Core Committee in 2003
- Approved by NTP Associate Director - Nov. 2005
- Expert panel roster completed and approved - June 2006
- Draft Expert Panel Report on Bisphenol A released - Dec. 2006



Application of Selection Factors to Bisphenol A

- U.S. Production > 10 million pounds/year
- Human exposure - food, water, and air
 - Food is main source
- Scientific literature - 67 developmental toxicity, 37 reproductive toxicity, and 43 exposure studies
- Public concern - yes
 - Possible low-dose effects



Lead Nomination

- Nominated by NIOSH in 2006
 - Concern for occupational exposures to lead
- A blood lead level of 40 $\mu\text{g}/\text{dL}$ is permitted in occupationally exposed workers, including pregnant women
- Some evidence of spontaneous abortion and reduced birth weight at $< 20 \mu\text{g}/\text{dL}$ in blood
- Does scientific evidence support lowering blood lead level limit?



Application of Selection Factors to Lead

- Production - several 100,000 tons/year
- Exposure - everyone is exposed
- Scientific literature - extensive
- Public concern - long-standing concern for neurotoxicity



Question

Should the NTP Board of Scientific Counselors have an advisory role in the selection of chemicals for CERHR Expert Panel evaluations?